K08 3693

PURITAN-BENNETT

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510(k) Summary

APR - 2 2009

Submitted by:	Puritan-Bennett Corporation 2200 Faraday Avenue Carlsbad, CA 92008
Company Contact:	Kim L. Bloom Sr. Regulatory Affairs Specialist Phone: (760) 603-5076 Fax: (760) 603-5350 kim.bloom@covidien.com
Date Summary Prepared:	December 11, 2008
Product Name:	840 Ventilator System with Leak Compensation
Common Name:	Ventilator
Classification:	Class II; Continuous Ventilator per 21 CFR §868.5895
Legally Marketed (Unmodified) Device:	• Puritan-Bennett Corp. 840 Ventilator System, K970460 • Puritan-Bennett Corp. 840 Ventilator System with Bilevel Ventilation, K984535 • Puritan-Bennett Corp. 840 Ventilator System with Neomode Option, K001646 • Puritan-Bennett Corp. 840 Ventilator System with Volume Ventilation Plus, K021573 • Puritan-Bennett Corp. 840 Ventilator System with Respiratory Mechanics, K063650 • Puritan-Bennett Corp. 840 Ventilator System with Proportional Assist Ventilation, K053388
Predicate Devices:	• Puritan-Bennett Corp. 840 Ventilator System with NeoMode, K001646 • Maquet Servo I, K073179 • Hamilton Medical, G5 Ventilator, K070513

Device Description:

The Leak Compensation Option enables the 840 Ventilator System to automatically detect and characterize gas flow that leaves the breathing circuit through air leak(s) and does not return to the 840's exhalation valve for inclusion in the displayed exhaled spirometry. LC does not makeup for lost delivered volume but does add the necessary additional flow into the breathing circuit to optimize breath triggering and cycling functions as well as maintain the set PEEP, and display clinically valuable leak-related parameters for consideration by the clinician. The Leak

Compensation feature is implemented on the 840 Ventilator through additional functionality in software and by use of the existing User Interface panel. No hardware or firmware changes or additions were required. The 840 Ventilator is a dual-microprocessor controlled, critical care ventilator intended to provide continuous ventilation for neonate to adult (with NeoMode Option) or infant to adult (without NeoMode Option) patients who require either invasive ventilation or non-invasive ventilation (via face mask).

Indications For Use:

The 840 Ventilator with Leak Compensation Option is intended to provide continuous ventilation to patients requiring respiratory support. The device is intended for patients with an Ideal Body Weight (IBW) as low as 0.5 kg (with NeoMode option) to adult, and for use in a wide variety of clinical conditions.

The 840 Ventilator with Leak Compensation Options is intended for a wide range of patients ranging from neonate to adult (V_T 5-2500 mL with NeoMode) or from infant to adult (V_T 25-2500 mL).

The 840 Ventilator with Leak Compensation is intended for use in hospital and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

Determination of Substantial Equivalence:

The intended use of the 840 Ventilator Leak Compensation is the same as that for conventional, currently marketed, critical care ventilators with similar functions. The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the device modification do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 840 Ventilator with Leak Compensation provides similar information as the predicate devices.

Information provided in this 510(k) submission provides comparative, predicate device information and describes development procedures that support the determination of substantial equivalence and assertion that the modified device is safe and effective for its intended use. Software design and development, (including verification and validation testing, test and software quality procedures) were conducted using FDA's Guidance for the Content of Pre-market Submissions for Software contained in medical devices, dated May 11, 2005 as a guidance and per internal company requirements.

In summary, Puritan-Bennett Corporation has provided information that indicates the 840 Ventilator with Leak Compensation to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices, incorporating similar functionality to those that have been previously cleared by FDA.

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification submission is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, 21 CFR § 807, Subpart E. A determination of substantial equivalency under this submission is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence in this submission shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Explanation of how intended use and fundamental scientific technology have not changed:

The 840 Ventilator with and without Leak Compensation is intended for use as continuous, critical care ventilator for patients requiring respiratory support. The modification, which adds Leak Compensation to the currently cleared 840 Ventilator, does not alter the intended use of the 840 Ventilator. The intended use and indication of the 840 Ventilator System with Leak Compensation Option, as described in its labeling, are the same as the intended use and indication for the 840 Ventilator System with NeoMode.

Based on the above comparative predicate information, the 840 Ventilator with Leak Compensation is substantially equivalent to the Puritan Bennett 840 Ventilator with NeoMode, the Maquet Servo I, and the Hamilton G5 Ventilator. The device modifications have not altered the fundamental scientific technology of the predicate device, the 840 Ventilator System with NeoMode. Furthermore, based on the descriptive information and risk analysis, the device modification does not raise significant or new questions of safety and effectiveness for the 840 Ventilator.

Summary of Performance Testing:

1. Functional testing confirms that the 840 Ventilator with Leak Compensation Ventilator is capable of meeting its stated performance specifications. The device passed all tests.
2. Testing confirms that the 840 Ventilator with Leak Compensation Ventilator complies with the applicable portions of the July 1995 "Draft Reviewer Guidance for Ventilators" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The device passed all applicable tests.
3. All software is tested in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 2005. The devices passed all tests.

Conclusions:

We conclude that the 840 Ventilator with Leak Compensation meets the stated performance specifications and criteria referenced above and that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kim L. Bloom
Senior Regulatory Affairs Specialist
Covidien
2101 Faraday Avenue
Carlsbad, California 92008

APR - 2 2009

Re: K083693
Trade/Device Name: PB 840 Ventilator System with Leak Compensation Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 17, 2009
Received: March 19, 2009

Dear Ms. Bloom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K083693

Device Name: PB 840 Ventilator System with Leak Compensation Option

Indications for Use:

The 840 Ventilator System with Leak Compensation Option is intended to provide continuous ventilation to patients requiring respiratory support. The device is intended for patients with an Ideal Body Weight (IBW) as low as 0.5 kg (with NeoMode option) to adult, and for use in a wide variety of clinical conditions.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) Subpart C)

AND/OR

Over-The-Counter Use _____ (21 CFR 801

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices